Attachment 3. 510(k) Summary

MAY 1 1 2010

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: K100406

1. Submitter's Identification:
   TaiDoc Technology Corporation
   3F, 5F, No.127, Wugong 2nd Rd., Wugu Township, Taipei County, 248, Taiwan

   Correspondence:
   Nicky Pan
   Regulatory Affairs Specialist
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   Date of submission: 02/12/2010

2. Device name:
   Proprietary name: FORA V20 blood glucose monitoring system

   Regulatory information:
   A. Regulation section: 21 CFR 862.1345 Glucose Test System
   B. Classification: Class II
   C. Product Code: CGA, Glucose Oxidase, Glucose
      NBW, System, Test, Blood Glucose, Over The Counter
   D. Panel: Chemistry (75)

3. Intended Use:

The FORA V20 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The alternative site testing in the FORA V20 Blood Glucose Monitoring System can be used only during steady-state blood glucose conditions.

The FORA V20 Blood Glucose Monitoring System contains a speaking functionality which provides step by step instructions to aid visually impaired persons.

4. Device Description:

The system consists of three main products: the meter, test strips, and control solutions. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only FORA V20 test strips and control solutions with the FORA V20 Blood Glucose Monitoring System.

5. Substantial Equivalence Information:

A. Predicate device name:

FORA TD-4245 Blood Glucose Monitoring System

B. Predicate K number: K083664

C. Comparison with predicate:

The modified FORA V20 Blood Glucose Monitoring Systems has the following similarities to the predicate device:

- same operating principle,
- same fundamental scientific technology,
- incorporate the same basic circuit design,
- incorporate the same materials,
- same shelf life

- packaged using the same materials, and
- manufactured by the same process.

The modifications encompass:

- Software modification to no-coding
- Addition of "no-coding" phrase on the labeling
- Addition of speaking function in Spanish
- Software modification to use mg/dL as the preset measurement.

6. Test Principle:
   The detection and measurement of glucose in blood is by an electrochemical biosensor technology using glucose oxidase.

7. Performance Characteristics:
   FORA V20 Blood Glucose Monitoring System has the same performance characteristics as the predicate device.

   A comparison of system accuracy performance demonstrated that the FORA V20 Blood Glucose Monitoring System and the currently marketed FORA TD-4245 Blood Glucose Monitoring System are substantially equivalent.

   Software verification and validation testing confirmed that the performance, safety and effectiveness of the FORA V20 Blood Glucose Monitoring Systems are equivalent to the predicate device.

8. Conclusion:
   Based on the information provided in this submission, the FORA V20 Blood Glucose Monitoring System is substantially equivalent to the predicate FORA TD-4245 Blood Glucose Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

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c/o Nicky Pan
Specialist of Regulatory Affairs
3F, 5F, No. 127, Wugong 2nd Rd Wugu Township
Taipei County, China (Taiwan) 248

MAY 11 2010

Re: k100406
Trade name: FORA V20 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: April 16, 2010
Received: April 16, 2010

Dear Nicky Pan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K100406

Device Name: FORA V20 Blood Glucose Monitoring System

Indications for Use:

The FORA V20 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K100406